REMARKS/ARGUMENTS

Applicants have studied the Office Action dated March 17, 2008 **and have made amendments to the claims**. It is submitted that the application, **as amended**, is in condition for allowance. By virtue of this **amendment**, claims 1 to 97 remain in the application. Claims 1 to 6, 10 to 21, 24 to 29, 40 to 60, 65 to 67, 70 to 72, 75 to 77, 80 to 82, 85 to 87, 90 to 92, and 95 to 97 are subject to examination. Claims 1, 15, 16, 20, and 25 have been amended. Claims 7 to 9, 22, 23, 30 to 39, 61 to 64, 68, 69, 73, 74, 78, 79, 83, 84, 88, 89, 93, 94, 98 to 109 have been withdrawn from examination.

Reconsideration and allowance of the pending claims in view of the above amendments and the following remarks is respectfully requested.

In the Office Action, the Examiner:

I. (Pgs. 2-3) rejected claims 1-4, 10, 11, 40, 47, and 65-67 under 35 U.S.C. § 102(b) as being fully anticipated by U.S. Patent No. 6,319,278 to Quinn;

II. (Pgs. 3-4) rejected claims 1-4, 6, 10, 14, 15, 18, 19, 40, 41, 43, 47, 49, 53, 65 to 67, 70 to 72, and 80 to 82 under 35 U.S.C. § 102(b) as being fully anticipated by International Patent Publication No. WO 99/37242 to Philips et al. (hereinafter "Philips");

III. (Pg. 4) rejected claims 25 to 29, 45, 46, 57, 59, 90 to 92, and 95 to 97 under 35 U.S.C. § 102(b) as being fully anticipated by U.S. Patent Publication No. 2003/88305 to Van Schie et al. (hereinafter "Van Schie");

IV. (Pg. 5) rejected claims 5, 12, 13, 16, 17, and 42 under 35 U.S.C. § 103(a) as being unpatentable over Philips in view of U.S. Patent No. 6,821,291 to Bolea et al. (hereinafter "Bolea");

V. (Pg. 5) rejected claims 16, 17, 51, and 75 to 77 under 35 U.S.C. § 103(a) as being unpatentable over Van Schie in view of Bolea;

VI. (Pgs. 6-7) rejected claims 18, 19, 20, 21, 24 to 29, 53, 57, 59, 80 to 82, 85 to 87, 90 to 92, and 95 to 97 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,099,558 to White et al. (hereinafter "White") in view of U.S. Patent No. 6,464,719 to Jayaraman;

VII. (Pgs. 7-8) rejected claim 48 under 35 U.S.C. § 103(a) as being unpatentable over Quinn in view of U.S. Patent No. 6,346,118 to Baker et al. (hereinafter "Baker");

VIII. (Pg. 8) rejected claims 48, 50, and 54 under 35 U.S.C. § 103(a) as being unpatentable over Philips in view of Baker;

IX. (Pgs. 8-9) rejected claims 58 and 60 under 35 U.S.C. § 103(a) as being unpatentable over Van Schie in view of Baker;

X. (Pg. 9) rejected claim 52 under 35 U.S.C. § 103(a) as being unpatentable over Van Schie in view of Bolea;

XI. (Pg. 9) rejected claims 54, 56, 58, and 60 under 35 U.S.C. § 103(a) as being unpatentable over White in view of Jayaraman and further in view of Baker; and

XII. (Pgs. 9-10) rejected claims 20, 21, 24, 44, 55, and 85 to 87 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,723,003 to Winston et al. (hereinafter "Winston") in view of Philips.

I. (Pgs. 2-3) Rejection under 35 U.S.C. § 102(b) Quinn

As noted above, the Examiner rejected claims 1-4, 10, 11, 40, 47, and 65-67 under 35 U.S.C. § 102(b) as being fully anticipated by Quinn. Reconsideration of the application is requested.

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (emphasis added by appellants); *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) ("A claim is anticipated only if **each and every element** as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Emphasis added.). According to the single source rule, all the claim's limitations must be contained in a single reference, *see, e.g., Brown v. 3M,* 265 F.3d 1349, 1351 (Fed.Cir.2001), and the reference "must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed in the prior art and that such existence would be recognized by persons of ordinary skill in the field of the invention." *Crown Operations Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375 (Fed.Cir.2002). Thus, if only one of the elements is not shown by the cited prior art reference, then the Section 102 rejection fails.

As will be explained below, it is believed that claim 1 was patentable over Quinn in its original form and, therefore, claim 1 has not been amended to overcome the reference.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claim 1, as amended calls for a vascular repair device, including:

> a curved, metallic, longitudinal support member:
>
> > having a graft body centerline parallel to a longitudinal axis of the graft body; and
> >
> > when viewed in an orientation where the longitudinal axis and the centerline are aligned with one another, the support member is substantially reverse-mirror symmetrical with respect to that longitudinal axis.

Simply stated, the support member of claim 1 is (1) connected to the graft body and is (2) reverse-mirror symmetrical in a particular viewed orientation.

Quinn discloses a cylindrical stent graft in FIGS. 1 to 3 and a bifurcated stent graft in FIGS. 4, 5, and 8. The cylindrical stent graft does not have a curved support member. The struts 20, 21, 22 are straight. The Quinn bifurcated stent graft has struts 46, 47, 48, 52 that are curved. However, in contrast to the claimed invention, these strut members 46, 47, 48, 52 are not connected to the graft body in any way. Instead, as set forth at col. 2, lines 32 to 35: "Struts 20, 21, and 22 extend between first and second stents 12 and 14, as shown. Struts 20-22 are constructed of fine gauge stainless steel spring wire or nitinol having a diameter of about 0.3 to 0.6 mm. Struts 20-22 **are attached to stents 12 and 14 in any suitable manner, such as soldering to outer elbows 18 at solder joint 24; they may, alternatively be attached by bending, or cut from a single piece of metal.**" Emphasis added by applicants. Never does Quinn disclose, describe, or suggest attaching any of the struts to the graft tube 31 or graft material 61. Because Quinn does not have this required element, it cannot anticipate claim 1 of the instant application.

Claim 1 of the instant application also requires the support member to be "reverse-mirror symmetrical" when a centerline of support member is visually aligned with the graft body's central longitudinal axis. The only curved strut in Quinn is illustrated in FIG. 4. Struts 46 and 52 are, in no way, analogous to this claimed feature. The other struts 47 and 48 are curved,

however, there is no indication in Quinn that these struts are reverse-mirror symmetrical. Merely because they are shown with a bend does not mean that they are "reverse-mirror symmetrical." Additionally, claim 1 requires that the centerline of the support member be aligned with the central longitudinal axis of the graft body. The bifurcated stent graft of FIGS. 4 and 5 of Quinn cannot have a central longitudinal axis because is it not cylindrically symmetrical. Therefore, the stents 47, 48 cannot be viewed along a non-existent central longitudinal axis to equate to the required feature of claim 1. Thus, for this reason, Quinn cannot be said to anticipate the features of claim 1.

Clearly, Quinn does not show a vascular repair device as recited in claim 1 of the instant application.

It is accordingly believed to be clear that no reference shows or suggests the features of claim 1. Claim 1 is, therefore, believed to be patentable over the art. The rejected dependent claims are believed to be patentable as well because they all are ultimately dependent on claim 1.

II. (Pgs. 3-4) Rejection under 35 U.S.C. § 102(b) Philips

As noted above, the Examiner rejected claims 1-4, 6, 10, 14, 15, 18, 19, 40, 41, 43, 47, 49, 53, 65 to 67, 70 to 72, and 80 to 82 under 35 U.S.C. § 102(b) as being fully anticipated by Philips. Reconsideration of the application is requested.

The rejection has been noted and the claims have been amended in an effort to even more clearly define the invention of the instant application. Support for the changes is found, for example, in FIG. 2 of the specification of the instant application.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claims 1 and 15, as amended, call for a vascular repair device, including:

> a structural framework having at least two Z-stents connected circumferentially to a graft body; and

a curved, metallic, longitudinal support member:

having a centerline at the graft body parallel to a longitudinal axis of the graft body; and

when viewed in an orientation where the longitudinal axis and the centerline are aligned with one another, the support member is substantially reverse-mirror symmetrical with respect to that longitudinal axis.

Thus, not only is the support member of claims 1 and 15 reverse-mirror symmetrical *in a particular orientation* (see bold text), the structural framework of the stent graft must have at least two Z-stents. Z-stents are well-defined in the art and also are defined in the specification. Page 2 of the specification cites U.S. Patent No. 5,282,824 to Gianturco as describing "a zig-zag-shaped, self-expanding stent commonly referred to as a z-stent."

In complete contrast, Philips discloses something entirely different from a Z-stent. Philips' singular wire, traversing all over the graft body, is in no way analogous to the Z-stent of claims 1 and 15. In particular, the Philips stent graft is fabricated from a flexible sheet of graft material (rectangular or trapezoidal shaped) that is laid flat while a single sinusoidal reinforcing wire is sewn thereto. See Philips at page 22, lines 1-5. After securing the one wire, the two lateral sides of the graft material are fastened to one another to form the tubular stent graft. In such an orientation, the lateral end loops of the sinusoidal wire are interdigitated as shown in FIG. 6a or touch one another at the longitudinal suture line of the graft body as shown in FIG. 6b. This single wire is present in every orientation of Philips and is required to carry out the function intended by the Philips inventors. On pages 3 and 12, this feature is clearly indicated: "the reinforcement elements extending annularly around the tube"; and "sinuous arrangement where opposed bends are overlapped and interdigitated . . can assist in imparting columnar strength to the tubular body."

Simply put, the kind of stent graft described by Philips is in no way reminiscent to the multiple Z-stent structural stent graft of claims 1 and 15.

Philips does not show a vascular repair device as recited in claims 1 and 15 of the instant application.

It is accordingly believed to be clear that no reference shows or suggests the features of claims 1 and 15. Claims 1 and 15 are, therefore, believed to be patentable over the art. Claims ultimately dependent on claims 1 or 15 are believed to be patentable as well due to this dependency.

With regard to claim 18, on page 4 of the Office action, the following argument is proffered: "since there are end stents **M** and the wire support member does not extend the entire distance between these ends stents, the stent graft forms a gimbal at an end." This conclusion, however, is not true. After a thorough examination of each of the twenty-eight (28) pages of drawings and of the specification, Philips reveals that it does not disclose any embodiment where the "wire support member does not extend the entire distance between these ends stents" as alleged in the rejection. Even the portion 44 shown in FIG. 5 of Philips has a vertical portion of the wire 32 extending between the section 46 of low-density pitch and the section 42 of high-density pitch. While section 40 does not have *transverse* portions of the wire 32, it does have *vertical* (i.e., longitudinal) portions of the wire 32. Therefore, this section 44 cannot be considered "free" from the support wire 32 as argued. It is true that the region 306 in FIGS. 24a and 24b is not covered by graft material 300, 308. Nonetheless, this region 306 contains vertical supporting wires – at least six of them!

In claim 18, a gimbal is present based on two features of the claim:

1) the structural framework has two pairs of stents each respectively connected to the proximal and distal ends thereof, these two pairs of stents defining a separation distance therebetween; and

2) the "longitudinal support member" is shorter than this separation distance and is connected to the graft body between the pairs of stents to, thereby, form a gimbal at one of the proximal and distal ends.

This means that the *longitudinal* support member needs to be absent somewhere between a pair of stents. Philips does not disclose any embodiment where the *longitudinal* support member is

absent as required by claim 18. Thus, a gimbal as defined in the instant application is not present or even suggested in Philips.

It is accordingly believed to be clear that no reference shows or suggests the features of claim 18. Claim 18 is, therefore, believed to be patentable over the art. Claims ultimately dependent on claim 18 are believed to be patentable as well due to this dependency.

III. (Pg. 5) Rejection under 35 U.S.C. § 102(b) Van Schie

As noted above, the Examiner rejected claims 25 to 29, 45, 46, 57, 59, 90 to 92, and 95 to 97 under 35 U.S.C. § 102(b) as being fully anticipated by Van Schie. Reconsideration of the application is requested.

The rejection of independent claim 25 has been noted and it has been amended in an effort to even more clearly define the invention of the instant application. Support for the changes is found, for example, in FIG. 1 of the specification of the instant application.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claim 25, as amended, call for a vascular repair device, including:

> a structural framework having at least two pairs of stents each respectively connected to said graft body at the proximal and distal ends, each of the pairs define respective outer and inner stents; and
>
> a curved longitudinal support member:
>
> > with two ends and a portion between the two ends curved partially around the circumference of the tubular graft body; and
> >
> > connected to the graft body between both of said inner stents of said two pairs of stents.

The elastic material 8 that is being compared to the support member of claim 25 is always depicted in Van Schie as a straight line extending from a first anchor point 9 to a second anchor point 10. The only curve in the alleged "support member" 8 is that illustrated in FIG. 2 of Van Schie. The curve, however, exists only in the innermost anterior straight line of the bent graft

tube 1, which tube has a circumference *orthogonal to* this straight line. This means that the curved member 8 does not extend laterally around a portion of the circumference of the graft tube 1.

Claim 25 has been amended to require the support member to have at least a portion thereof "curved partially around the circumference of the tubular graft body." Nowhere does Van Schie suggest, let alone disclose, curving any portion of the material 8 *circumferentially*. The material 8 *only* exists in a straight line in Van Schie.

It is accordingly believed to be clear that no reference shows or suggests the features of claim 25. Claim 25 is, therefore, believed to be patentable over the art. Claims ultimately dependent on claim 25 are believed to be patentable as well due to this dependency.

As will be explained below, it is believed that claim 28 was patentable over Van Schie in its original form and, therefore, claim 28 has not been amended to overcome the reference.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claim 28 calls for a vascular repair device, including:

> a tubular graft body having first and second ends;
>
> a structural framework having at least three stents, two of the stents being connected to the tubular graft body adjacent the first end, the two stents being separated from one another on the graft body to define an outer stent and an inner stent, a third of the stents being connected to the tubular graft body adjacent the second end; and
>
> a longitudinal support member connected to the graft body between the inner stent and the third stent **without touching the inner stent** and the third stent.

The feature of Van Schie alleged in the rejection to be similar to the support member of claim 28 is the elastic material 8 shown in FIGS. 1 and 2. The Examiner correctly notes that, in paragraph [0047] Van Schie recites the following:

> It may be noted that the elastic material may not extend the entire length of the prosthesis but may be used on only part of the length of the prosthesis so that the prosthesis when placed may have a curved portion and a straight portion.

Claim 28 requires that the support member be connected to the graft body but **to not touch both (1)** the inner stent of a pair of stents at one extreme end of the graft body **and (2)** the third stent at the other extreme end of the graft body. The description of the material 8 of Van Schie exists only in paragraphs [0043] to [0047] and the text in paragraph [0045] requires the material 8 to be "fastened" to the prosthesis. Paragraph [0048] et seq. talk about embodiments that are not related to the material 8 shown in FIGS. 1 and 2. By illustrating the curved prosthesis in FIG. 2 with the elastic material 8 touching the graft material tube 1 *throughout its extent*, Van Schie expressly indicates that the material 8 touches the stent graft *along its entire extent*. If this were not true, then the material 8 would form a band extending in a perfect straight line from point 9 to point 10 (much like a string of a bow). FIGS. 1 and 2 further show that all intermediate stents 4 are attached to the outer side of the tube 1 and that the extreme stents 5, 6 are attached to the inner side of the tube 1. The intermediate stents 4 are the only ones that can be compared to the "inner stent" of claim 28. Therefore, if the material 8 touches the tube 1 along its whole length, by definition, *the material 8 must touch every one of the intermediate ("inner") stents 4*. Claim 28 requires the inner stent to **not touch** the support member. Accordingly, Van Schie cannot anticipate the features of claim 28.

It is accordingly believed to be clear that no reference shows or suggests the features of claim 28. Claim 28 is, therefore, believed to be patentable over the art. Claims ultimately dependent on claim 28 are believed to be patentable as well due to this dependency.

IV. (Pg. 5) Rejection under 35 U.S.C. § 103(a) Philips and Bolea

As noted above, the Examiner rejected claims 5, 12, 13, 16, 17, and 42 under 35 U.S.C. § 103(a) as being unpatentable over Philips in view of Bolea. Reconsideration of the application is requested.

In section II above, applicants detailed the reasons why Philips did not relate to the features of instant invention. These arguments are equally applicable herein with regard to independent

claim 16 and are, therefore, incorporated herein by reference. In summary, Philips discloses a singular wire, traversing all over the graft body, that is in no way analogous to the Z-stent of claim 16. The Philips stent graft is fabricated from a flexible sheet of graft material (rectangular or trapezoidal shaped) that is laid flat while a **single sinusoidal reinforcing wire** is sewn thereto. See Philips at page 22, lines 1-5. After securing the one wire, the two lateral sides of the graft material are fastened to one another to form the tubular stent graft. The kind of stent graft described by Philips is entirely different from the multiple Z-stent structural stent graft of claim 16. In an effort to even more clearly define the invention of the instant application and its applicability to Z-stent circumferential structures, Claim 16 has been amended. Support for the changes is found, for example, in FIG. 1 of the specification of the instant application.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claim 16, as amended, calls for a vascular repair device, including:

> a tubular graft body;
>
> a structural framework having at least two Z-stents connected circumferentially to said tubular graft body; and
>
> a longitudinal support member connected to said graft body independent of said structural framework and having two ends, at least one of said ends having a longitudinal extremity curved back upon itself.

In this combination rejection, the Examiner admits that "Philips fails to disclose the longitudinal member has looped ends at the extremities." In an attempt to overcome this deficiency, Bolea is combined because it allegedly teaches "(Fig. 22) a stent with a wire member having looped extremities 184. Bolea et al. also teach that the loops enable an end to be collapsed to **remove** the stent device, col. 10, lines 31-36." (Emphasis added by applicants.) FIG. 22 clearly shows that these loops 184 are formed at longitudinal ends of **multi-wire braided** stents having "a mesh structure." Bolea at col. 4, line 40; see also FIGS. 1, 2, 5, 7, 8, 10, 11, 12, 14, 15, 16, 18, 19, 20, 21, 22, and 23. In its proper context, Bolea teaches placement of loops at the extreme ends of a "collapsing element [formed as] a discontinuous spiral 180." This element assists in collapsing of the tubular graft. Thus, instead of placing the loops on a structure that *provides* longitudinal support, the loops 184 are placed on a device that *removes* longitudinal support!!!

Simply put, Bolea teaches application of the loops to ends of something that teaches a function entirely at odds with the "longitudinal support member" of claim 16.

Because Philips and Bolea both do not relate to Z-stent stent grafts, this looped-end teaching simply is not relevant to the Z-stent art that is applicable to the instant invention. In fact, it teaches exactly in the opposite direction of the instant claims.

The Supreme Court holds that "when the prior art **teaches away** from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR*, 127 S. Ct. at 1740 (emphasis added). Here, the combination of Philips and Bolea teach away from inserting a collapsing element onto a single-snaked-wire stent having no Z-stents and no longitudinal support member.

If, for the sake of argument, such a combination could be accepted, then one having ordinary skill in the art would not be taught to apply the Bolea loops to a non-existent longitudinal support member of Philips. Instead, that person would be taught to apply the loops *to the only two ends of the single snaking wire 16 of Philips*!

There is only one argument that is provided with respect to completing this two-reference combination rejection. This argument is set forth in its entirety as follows:

> It would have been obvious to one of ordinary skill in the art to use looped ends on a longitudinal wire support member as taught by Bolea et al. and incorporate into the stent graft of Philips et al. to *provide the ability to remove the prosthesis if necessary.*

This single, half-sentence clause to make a combination rejection is the exact kind of reasoning frowned upon by the Supreme Court. In *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (April 30, 2007), the Supreme Court states that the "analysis [of obviousness] should be made explicit. See *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")." Here, there is no such explicit analysis, just a single conclusory statement.

Thus, the burden of showing how these references can possibly suggest applying a loop to a longitudinal support member has not been met, especially where neither Philips nor Bolea actually have a longitudinal support member.

The Supreme Court has held that the Federal Circuit's teaching, suggestion, or motivation test is not inconsistent with the analysis set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), and can be used in the "expansive and flexible approach" of determining obviousness *vel non*. *KSR*, 127 S. Ct. at 1739. See also *DyStar Textilfarben GmbH & Co. Deutschland KG. v C.H. Patrick Co.*, 464 F. 3d 1356, 1367 (Fed. Cir. 2006) (flexible approach); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1291 (Fed. Cir. 2006) (flexibility in obviousness jurisprudence). Applied to the circumstances here, there is no teaching, no suggestion, and no motivation to arrive at the features of the instant claims.

It is well settled that almost all claimed inventions are but novel combinations of old features. The courts have held in this context, however, that when "it is necessary to select elements of various teachings in order to form the claimed invention, we ascertain whether there is any suggestion or motivation **in the prior art** to make the selection made by the applicant". *Interconnect Planning Corp. v. Feil*, 227 USPQ 543, 551 (Fed. Cir. 1985) (emphasis added). "Obviousness can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination". *In re Bond*, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990). "Under Section 103 teachings of references can be combined **only** if there is some suggestion or incentive to do so." *ACS Hospital Systems, Inc. v. Montefiore Hospital et al.*, 221 USPQ 929, 933, 732 F.2d 1572 (Fed. Cir. 1984) (emphasis original). "Although a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be '**clear and particular**.'" *Winner Int'l Royalty Corp. v. Wang*, 53 USPQ2d 1580, 1587, 202 F.3d 1340 (Fed. Cir. 2000) (emphasis added; citations omitted); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 56 USPQ2d 1456, 1459 (Fed. Cir. Oct. 17, 2000). Appellant respectfully believes that there is no "clear and particular" teaching or suggestion in Philips to incorporate the features of Bolea, and there is no "clear and particular" teaching or suggestion in Bolea to incorporate the features of Philips.

In establishing a *prima facie* case of obviousness, **it is incumbent upon the Examiner** to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion, or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the appellant's disclosure. See, for example, *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir. 1988), *cert. den.*, 488 U.S. 825 (1988). The requisite reason why one of ordinary skill in the art would have been led to modify Philips with Bolea or to combine Philips' teachings with Bolea's teachings to arrive at the claimed invention has not been provided.

The Examiner simply has failed to meet the burden for satisfying the above requirements to allow a combination rejection to stand.

It is accordingly believed to be clear that no reference shows or suggests the features of claim 16. Claim 16 is, therefore, believed to be patentable over the art. Claims ultimately dependent on claim 16 are believed to be patentable as well due to this dependency.

Finally, it is noted that all of the claims rejected in this section are dependent except for claim 16. Applicants respectfully believe that these dependent claims are believed to be patentable because of their ultimate dependency upon independent claims 1 and 16.

V. (Pg. 5) Rejection under 35 U.S.C. § 103(a) Van Schie and Bolea

As noted above, the Examiner rejected claims 16, 17, 51, and 75 to 77 under 35 U.S.C. § 103(a) as being unpatentable over Van Schie in view of Bolea. Reconsideration of the application is requested.

The rejection of independent claim 16 has been noted and it has been amended in an effort to even more clearly define the invention of the instant application. Support for the changes is found, for example, in FIG. 1 of the specification of the instant application.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claim 16, as amended, calls for a vascular repair device, including:

> a tubular graft body;
>
> a structural framework having at least two Z-stents connected circumferentially to said tubular graft body; and
>
> a longitudinal support member connected to said graft body independent of said structural framework and having two ends, at least one of said ends having a longitudinal extremity curved back upon itself.

In this combination rejection, the Examiner admits that "Van Schie et al. fail to disclose the support member extremity is curved back on itself." In an attempt to overcome this deficiency, Bolea is combined because it teaches "(Fig. 18) that wire support members are curved back on themselves to form loops 170 to retrieve the stent **at a later time**, see entire patent for reason of loops." (Emphasis added by applicants.) These loops 170 are formed with respect to **braided** stents having "a mesh structure." Bolea at col. 4, line 40; see also FIGS. 1, 2, 5, 7, 8, 10, 11, 12, 14, 15, 16, 18, 19, 20, 21, 22, and 23. In the context of Bolea, therefore, this reference teaches placement of loops at the extreme ends of some of the wires forming the "mesh structure." *Id.* In other words, Bolea teaches application of the loops to ends of the *circumferential* supporting structure – not the *longitudinal* supporting structure. Because Bolea does not relate to Z-stent stent grafts, this looped-end teaching simply is not relevant to the Van Schie Z-stent stent graft art. If, for the sake of argument, such a combination could be believed, then one having ordinary skill in the art would not be taught to apply the Bolea loops to the Van Schie elastic member 8. Instead, that person would be taught to apply the loops (such as loop 170 in FIG. 17) *to the apices of the stents 5, 6 in Van Schie and not to the longitudinal support structure 8*!

The only argument that has been provided with respect to completing this two-reference combination rejection is set forth in its entirety as follows:

> It would have been obvious to one of ordinary skill in the art to modify the extremities of the longitudinal support member as taught by Bolea et al. in the stent graft of Van Schie et al. *such that the ability to retrieve the stent graft can be accomplished easily if the need arises in the patient.*

What the Examiner indicates as the motivation for changing the Van Schie teaching with Bolea's looped ends is "*ability to retrieve the stent graft*" but the instant patent and, especially, claim 16 does not deal with the issue of retrieving the stent graft. Instead, it deals with a Z-stent circumferential structural framework and a "longitudinal support" member having a curved back end.

This single sentence obviousness conclusion is the exact kind of reasoning frowned upon by the Supreme Court. In *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (April 30, 2007), the Supreme Court states that the "analysis [of obviousness] should be made explicit. See *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")." Here, there is no such explicit analysis, just a single conclusory statement – and a statement that is entirely unrelated to longitudinal support. Thus, the burden of showing how these references can possibly suggest using a looped backed end on a longitudinal support member has not been met.

The Supreme Court holds that "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR*, 127 S. Ct. at 1740. The Supreme Court also has stated that "the effect of demands known to the design community or present in the marketplace" can supplement background knowledge possessed by one having ordinary skill in the art. *Id.* at 1740-1741. "[I]t often may be the case that market demand, rather than scientific literature, will drive design trends." *Id.* at 1741.

The Examiner seems to be following a feature in the art that permits retrieval of stent grafts. The feature at issue in this rejection has **nothing** to do with *retrieval* of stent grafts. In complete contrast to this, desirable aspects of the features of claim 16 include, for example, prevention of a puncture danger at the extreme ends of the longitudinal support member and improvement in the securing of the support member to the stent graft. A comparison of entirely unrelated features can only lead to one conclusion -- that one having ordinary skill in the art would not be

motivated in any way to address the issue solved by the invention with technology that is entirely unrelated to Z-stent stent grafts.

The Supreme Court has held that the Federal Circuit's teaching, suggestion, or motivation test is not inconsistent with the analysis set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), and can be used in the "expansive and flexible approach" of determining obviousness *vel non*. *KSR*, 127 S. Ct. at 1739. See also *DyStar Textilfarben GmbH & Co. Deutschland KG. v C.H. Patrick Co.*, 464 F. 3d 1356, 1367 (Fed. Cir. 2006) (flexible approach); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1291 (Fed. Cir. 2006) (flexibility in obviousness jurisprudence). Applied to the circumstances here, there is no teaching, no suggestion, and no motivation to arrive at the features of the instant claims.

It is well settled that almost all claimed inventions are but novel combinations of old features. The courts have held in this context, however, that when "it is necessary to select elements of various teachings in order to form the claimed invention, we ascertain whether there is any suggestion or motivation **in the prior art** to make the selection made by the applicant". *Interconnect Planning Corp. v. Feil*, 227 USPQ 543, 551 (Fed. Cir. 1985) (emphasis added). "Obviousness can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination". *In re Bond*, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990). "Under Section 103 teachings of references can be combined **only** if there is some suggestion or incentive to do so." *ACS Hospital Systems, Inc. v. Montefiore Hospital et al.*, 221 USPQ 929, 933, 732 F.2d 1572 (Fed. Cir. 1984) (emphasis original). "Although a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be '**clear and particular**.'" *Winner Int'l Royalty Corp. v. Wang*, 53 USPQ2d 1580, 1587, 202 F.3d 1340 (Fed. Cir. 2000) (emphasis added; citations omitted); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 56 USPQ2d 1456, 1459 (Fed. Cir. Oct. 17, 2000). Appellant respectfully believes that there is no "clear and particular" teaching or suggestion in Van Schie to incorporate the features of Bolea, and there is no "clear and particular" teaching or suggestion in Bolea to incorporate the features of Van Schie.

In establishing a *prima facie* case of obviousness, **it is incumbent upon the Examiner** to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion, or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the appellant's disclosure. See, for example, *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir. 1988), *cert. den.*, 488 U.S. 825 (1988). The requisite reason why one of ordinary skill in the art would have been led to modify Van Schie with Bolea or to combine Van Schie's teachings with Bolea's teachings to arrive at the claimed invention has not been provided.

A critical step in analyzing the patentability of claims pursuant to 35 U.S.C. § 103 is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *Id.* (quoting *W.L. Gore & Assocs. Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)).

Appellant respectfully believes that any teaching, suggestion, or incentive possibly derived from the prior art is only present with hindsight judgment in view of the instant application. "It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the appellant's structure as a template and selecting elements from references to fill the gaps." *In re Gorman*, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). The Examiner has attempted to meet his burden with an impermissible hindsight view of the **current** state of the art, thus, the combination rejection must fail.

Failure to meet the burden for satisfying the above requirements requires removal of the combination rejection.

It is accordingly believed to be clear that no reference shows or suggests the features of claim 16. Claim 16 is, therefore, believed to be patentable over the art. The dependent claims in the rejection ultimately depend upon claim 16 and, therefore, are likewise believed to be patentable as well due to this dependency.

VI. (Pgs. 6-7) Rejection under 35 U.S.C. § 103(a) White and Jayaraman

As noted above, the Examiner rejected claims 18, 19, 20, 21, 24 to 29, 53, 57, 59, 80 to 82, 85 to 87, 90 to 92, and 95 to 97 under 35 U.S.C. § 103(a) as being unpatentable over White in view of Jayaraman. Reconsideration of the application is requested.

As will be explained below, it is believed that claims 18 and 28 were patentable over White and Jayaraman in their original form and, therefore, these claims have not been amended to overcome the references. Claims 20 and 25 have been amended as set forth herein but not for reasons related to either or both of White or Jayaraman.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claims 18, 20, 25, and 28 each include features where a longitudinal support member has a length smaller than a distance between two stents of the stent graft to create a gimbal on at least one end thereof. Neither Jayaraman nor White disclose or even suggest such a feature and, therefore, a combination of the two cannot suggest such a feature. The arguments with regard to the gimbal feature set forth above are hereby incorporated by reference herein to prevent redundancy. Simply put, to have a gimbal at one end of a stent graft, there is a structural framework including stents and a longitudinal support member **terminating between two independent stents** (claim 18) or **prior to a second-to-last stent of a pair of stents** (claims 20, 25, 28). Jayaraman is entirely unrelated to such independent stents (e.g., circumferential Z-stents of claim 20). Thus, it can contribute nothing towards the suggestion of claims 18, 20, 25, or 28. With regard to White, the Examiner admits that it is entirely silent on the subject of supporting members: "White et al. fail to disclose a longitudinal support member." Office Action at 6. Therefore, there is no way to support a conclusion where either White, Jayaraman, or the combination thereof can suggest any aspect of the features of claims 18, 20, 25, or 28.

In an attempt to make up for the clear deficiency of White and to complete the combination rejection, the Examiner must *add* a feature of Jayaraman to White. Specifically, the Examiner states that "Jayaraman teaches (Fig. 8) a longitudinal support member 53 that is curved and shorter than the body of the stent graft and since it is joined to the graft, it is not touching the stents." There are two errors with this statement.

First, Jayaraman teaches a support member that extends from one longitudinal end of the expandable stent all the way to the other longitudinal end. Clearly shown in every embodiment is that the members 15, 53 either extend all the way to the ends of the mesh stent or extend virtually up to the ends. Even if one were to add Z-stents to the mesh expandable stent of Jayaraman (which applicants believe would be improper and unwarranted because it would serve no purpose for doing so and would be contrary to the mesh structure teaching of Jayaraman), there is not enough room at the ends of the mesh material 27, 35 to include such a stent so that the members 15, 53 can end prior to such a hypothetical addition thereto. In other words, Jayaraman teaches providing longitudinal support entirely from one end to the other, not shortening that support to end before at least a pair of stents on the tubular graft body.

Second, even though Jayaraman teaches attaching the members 15, 53 to the mesh tubular expandable stent, there is no teaching or even suggestion towards how those members 15, 53 would act if hypothetical circumferential stents were attached to the mesh structure. The instant claims require that the support member extend to **not touch the stent(s) that form the gimbal**. If there is no stent on the mesh expandable tube of Jayaraman, then there is no way that this reference could ever suggest how the members 15, 53 would not touch the stents in that hypothetical situation.

But, these situations are not what is being suggested in the combination rejection. What is being argued is that the members 15, 53 of Jayaraman should be added to the White stent graft. But, if the Jayaraman members 15, 53 extend all of the way to the ends of the mesh structure there, then adding such members 15, 53 to White would mean that the members 15, 53 should extend

virtually all the way to the ends of the White stent graft. This is not what is required in the rejected claims and, therefore, the rejection fails.

There is no possible suggestion in either White or Jayaraman to shorten the Jayaraman member 15, 53 to extend substantially less than that shown in every embodiment of Jayaraman. Nonetheless, this exact situation has been drafted in the hypothetical configuration shown on page 7 of the Office action. This configuration places a hypothetical sinusoidal support member that is longitudinally compressed as compared to the members 15, 53 in the Jayaraman disclosure. Clearly, there is no disclosure or suggestion in the Office action as to why this compression should occur so that the ends of the member 15, 53 falls within the end pairs of stents on the White stent graft. What has occurred here is that, after seeing the invention of the claims, the Examiner has with impermissible hindsight created a desired situation in a hypothetical figure. However, this creation finds no support in either reference or in the general teachings of stent grafts to make such modifications.

A critical step in analyzing the patentability of claims pursuant to 35 U.S.C. § 103 is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614,1617 (Fed. Cir. 1999). Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *Id.* (quoting *W.L. Gore & Assocs. Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)).

Any teaching, suggestion, or incentive possibly derived from the cited prior art is only present with hindsight judgment in view of the present application. "It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps. . . . The references **themselves** must provide some teaching whereby the applicant's combination would have been obvious." *In re Gorman*, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991) (emphasis added). Here, no such teaching is present in the cited references. In fact, the teaching of Jayaraman is

not in a direction *towards* the suggested combination. Rather, it is in the opposite direction because White is a Z-stent configuration; in such configuration, there are two or more circumferential supporting devices 17, 17a that radially support a tubular graft about its circumference. In complete contrast, Jayaraman is a tubular stent having a cylindrical fabric tube with multiple serpentine shaped *longitudinal* pieces that are fastened to the tube along *longitudinal lines*; they are not fastened along circumferential lines.

The Jayaraman device is a stent, it does not have stents (plural) as defined in the instant application (see page 2, lines 9 to 14, citing U.S. Patent Nos. 5,282,824 and 5,507,771) and as known and referred to in the art. In particular, Jayaraman does not have the **"at least two stents"** required by claim 18, the **"at least two pairs of stents"** required by claims 20 or 25, or the **"at least three stents"** required by claim 28. In fact, to have "at least two stents" in the Jayaraman disclosure would mean that there would have to be two entire tubular structures each having the sets of serpentine connecting pieces. Nowhere does Jayaraman disclose entirely duplicating, triplicating, or quadrupling itself.

Jayaraman does not even relate to prostheses that use stents or, especially, Z-stents; the entire Jayaraman device *is a stent*. Merely because the title of Jayaraman uses the word "stent" does not mean that it relates to the kind of technology that utilizes the plurality of circumferential Z-stents that is described in detail in the instant application. Accordingly, there can be no motivation anywhere within the Jayaraman disclosure to implement the *tubular* mesh stent technology of Jayaraman in the *Z-stent intraluminal stent graft* disclosed in White.

The Supreme Court has held that the Federal Circuit's teaching, suggestion, or motivation test is not inconsistent with the analysis set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), and can be used in the "expansive and flexible approach" of determining obviousness *vel non*. *KSR*, 127 S. Ct. at 1739. See also *DyStar Textilfarben GmbH & Co. Deutschland KG. v C.H. Patrick Co.*, 464 F. 3d 1356, 1367 (Fed. Cir. 2006) (flexible approach); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1291 (Fed. Cir. 2006) (flexibility in obviousness jurisprudence). Applied to the circumstances here, there is no teaching, no suggestion, and no motivation to arrive at the features of the instant claims.

It is well settled that almost all claimed inventions are but novel combinations of old features. The courts have held in this context, however, that when "it is necessary to select elements of various teachings in order to form the claimed invention, we ascertain whether there is any suggestion or motivation **in the prior art** to make the selection made by the applicant". *Interconnect Planning Corp. v. Feil*, 227 USPQ 543, 551 (Fed. Cir. 1985) (emphasis added). "Obviousness can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination". *In re Bond*, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990). "Under Section 103 teachings of references can be combined **only** if there is some suggestion or incentive to do so." *ACS Hospital Systems, Inc. v. Montefiore Hospital et al.*, 221 USPQ 929, 933, 732 F.2d 1572 (Fed. Cir. 1984) (emphasis original). "Although a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be '**clear and particular**.'" *Winner Int'l Royalty Corp. v. Wang*, 53 USPQ2d 1580, 1587, 202 F.3d 1340 (Fed. Cir. 2000) (emphasis added; citations omitted); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 56 USPQ2d 1456, 1459 (Fed. Cir. Oct. 17, 2000). There is no "clear and particular" teaching or suggestion in Jayaraman to incorporate the features of White, and there is no teaching or suggestion in White to incorporate the features of Jayaraman.

In establishing a *prima facie* case of obviousness, it is **incumbent upon the Examiner** to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion, or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the applicants' disclosure. See, for example, *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir. 1988), *cert. den.*, 488 U.S. 825 (1988). The only reason provided as to why one of ordinary skill in the art would have been led to modify Jayaraman or White or to combine Jayaraman's and White's teachings to arrive at the claimed vascular repair device invention is set forth as "it provides more support to the vessel walls and assist [sic] in expansion and keep the

stent in its expanded form together." Office action at 6. However, White does not provide any reason why additional vessel support would be needed in addition to the support already provided by White. Nor does White provide any reason why the White stent graft needs to be kept "in its expanded form together." These reasons seem to be set forth without looking to White's desire to improve upon the design already set forth. It is known to those skilled in the art that stent grafts having longitudinal support that is too strong will not perform well or will not perform at all. The Examiner has provided no reason why this hypothetical combination of the members 15, 53 onto the White disclosure would not render useless the support struction of the White stent graft. In fact, placing one or more such members 15, 53 around the circumference of the White stent graft will make the stent graft so inflexible that it cannot traverse curved vasculature and, instead of assisting in improvement of the vessel, can destroy the vessel if it cannot bend through the tortous paths of common vasculature. Applicants, therefore, submit that the combination will not function as White would have intended.

More specifically, the Examiner contends that the S-shaped connecting pieces 53 of Jayaraman would "provide more support to the vessel walls and assist in expansion" if added to White. This conclusion, however, is unsupported and incorrect. There would be no assistance in the expansion of the White stent graft if the connecting pieces 53 of Jayaraman were added to White. **In fact, the opposite is true** because any relatively rigid pieces attached to the graft tube of White would *prevent expansion*, not "assist in expansion" as asserted by the Examiner. If such a combination was hypothetically made, at best, there would be *no* affect on expansion and, at worst, expansion would be *hindered* by adding the rigid pieces of Jayaraman to White.

Jayaraman clearly discloses that many of the connecting pieces 53 must be disposed about the circumference of the tubular body. There is no suggestion to use only one of the connecting pieces 53 in Jayaraman in any way and, especially, there is no hint or suggestion in White to make such a drastic change in the Jayaraman device. In fact, if one were to add multiple connecting pieces 53 to White (which is what is actually disclosed by Jayaraman), the resulting hypothetical stent graft would be significantly or dangerously rigid about its longitudinal axis and would, therefore, *be dangerous when traversing curved vessels and not be able to be*

implanted in curved vessels – thus, totally eliminating a desirable feature of stent grafts! Such a hypothetical combination, therefore, would *defeat White's intended purpose.*

The Examiner cited FIG. 8 of Jayaraman for the feature that is added to White to form the combination rejection. It is significant to note that there is nothing to show or suggest in Jayaraman that the FIG. 8 prosthesis could ever function as a stent graft or even relate to a stent graft because there is no force applied by the connecting piece 53 that could ever assist in keeping the lumen of the material fabric tube 51 open after being implanted in a vessel. As such, the combination of these two different features cannot be supported.

Clearly, the combination of Jayaraman and White do not suggest the vascular repair device as recited in any of claims 1, 15, 16, 18, 20, 25, or 28 of the present application.

VII. (Pgs. 7-8) Rejection under 35 U.S.C. § 103(a) Quinn and Baker

As noted above, the Examiner rejected claim 48 under 35 U.S.C. § 103(a) as being unpatentable over Quinn in view of U.S. PatentNo. 6,346,118 to Baker et al. (hereinafter "Baker") Reconsideration of the application is requested.

Insofar as claim 48 is ultimately dependent upon claim 1, it is respectfully believed that this claim is allowable based upon this dependency. All arguments set forth above with regard to claim 1 are hereby incorporated by reference herein.

VIII. (Pg. 8) Rejection under 35 U.S.C. § 103(a) Philips and Baker

As noted above, the Examiner rejected claims 48, 50, 54 under 35 U.S.C. § 103(a) as being unpatentable over Philips in view of Baker. Reconsideration of the application is requested.

Insofar as claims 48, 50, and 54 are ultimately dependent upon claims 1, 15, or 18, it is respectfully believed that these claims are allowable based upon this dependency. All arguments set forth above with regard to claims 1, 15, and 18 are hereby incorporated by reference herein.

IX. (Pgs. 8-9) Rejection under 35 U.S.C. § 103(a) Van Schie and Baker

As noted above, the Examiner rejected claims 58 and 60 under 35 U.S.C. § 103(a) as being unpatentable over Van Schie in view of Baker. Reconsideration of the application is requested.

Insofar as claims 58 and 60 are ultimately dependent upon claims 25 and 28, it is respectfully believed that these claims are allowable based upon this dependency. All arguments set forth above with regard to claims 25 and 28 are hereby incorporated by reference herein.

X. (Pg. 9) Rejection under 35 U.S.C. § 103(a) Van Schie and Bolea

As noted above, the Examiner rejected claims 52 under 35 U.S.C. § 103(a) as being unpatentable over Van Schie in view of Bolea. Reconsideration of the application is requested.

Insofar as claim 52 is ultimately dependent upon claim 16, it is respectfully believed that this claim is allowable based upon this dependency. All arguments set forth above with regard to claim 16 is hereby incorporated by reference herein.

XI. (Pg. 9) Rejection under 35 U.S.C. § 103(a) Jayaraman Baker

As noted above, the Examiner rejected claims 54, 56, 58, and 60 under 35 U.S.C. § 103(a) as being unpatentable over White in view of Jayaraman and further in view of Baker. Reconsideration of the application is requested.

Insofar as claims 54, 56, 58, and 60 are ultimately dependent upon claims 18, 20, 25, and 28, it is respectfully believed that these claims are allowable based upon this dependency. All arguments set forth above with regard to claims 18, 20, 25, and 28 are hereby incorporated by reference herein.

XII. (Pgs. 9-10) Rejection under 35 U.S.C. § 103(a) Winston and Philips

As noted above, the Examiner rejected claims 20, 21, 24, 44, 55, and 85 to 87 under 35 U.S.C. § 103(a) as being unpatentable over United States Patent No. 5,723,003 to Winston et al. in view of Philips. Reconsideration of the application is requested.

The rejection has been noted and claim 20 has been amended in an effort to even more clearly define the invention of the instant application. Support for the changes is found, for example, in FIG. 1 of the specification of the instant application.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claim 20, as amended, calls for a vascular repair device, including:

> a structural framework having at least **first and second pairs of Z-stents** each respectively connected to the graft body adjacent the proximal end and the distal end, the stents of each of the first and second pairs of stents being separated from one another at the graft body to define **a respective outer stent and a respective inner stent**; and
>
> a **longitudinal, metallic support member** connected to the graft body and an entirety thereof **extending between:**
>
> **the inner stent of the first pair of stents; and**
>
> **the outer stent of the second pair of stents.**

Winston has been introduced in this rejection as relevant to the subject matter of claim 20 and applicants respectfully believe that, with this clarifying amendment, cannot be relevant to the features of the claims for a variety of reasons. First, Winston discloses two different kinds of stents 12, 14, both of which are entirely different in structure and form than a Z-stent of claim 20. Winston does not have, disclose or even tangentially suggest use of a Z-stent let alone a set of two pairs of Z-stents at proximal and distal ends of the graft material. Second, the Examiner admits that "Winston et al. fail to disclose a longitudinal support member." Office action at 10. This is because Winston addresses a technology that intentionally does not include longitudinal support members. The graft material that exists between the stents 12, 14 is shown, in every embodiment, as being concertina shaped so that longitudinal expansion and retraction is **permitted**. Inclusion of a longitudinal **support** member would defeat that ability to move longitudinally. As such, Winston teaches in a direction entirely at odds with incorporating the longitudinal support member of claim 20. Without providing any suggestion towards a longitudinal support member, it is axiomatic that it does not suggest the precise orientation of the support member between the inner and outer stents as required in claim 20.

Philips has been addressed above in detail and that explanation has clearly set forth that Philips has no relevance to Z-stents as they are known in the art. The arguments related to Philips above is incorporated herein by reference in its entirety. In summary, Philips has a flat graft material on which is attached a single sinusoidal material that, when the two sides of the graft material are connected together, traversed back and forth around the circumference from one end to the other. This stent graft does not refer to or suggest use of Z-stents as set forth in the instant application and in claim 20, in particular. As set forth on page 10 of the Office action, Philips is being added to Winston such that it "provides more support to the stent graft and prevents kinking when the stent graft is bent in tortuous vessels." This argument, however, is entirely at odds with the intentional configuration of loose concertina portions between each stent in the Winston device. A longitudinal support member would not ***help*** the features of the Winston device, it would adversely affect it. Therefore, one having ordinary skill in the art would not look to combining Philips with Winston as suggested in the Office action.

KSR Int'l Co. v. Teleflex, Inc., 127 S. Ct. at 1741, requires that the Examienr make explicit the analysis of obviousness. See *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")." Here, there is no such explicit analysis, just a single conclusory statement, as set forth above, that is entirely at odds with the disclosure to which the new feature is being added. As such, there can be no conclusion that the burden of showing how these references can possibly suggest the features of claim 20 has been met.

The Supreme Court holds that "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR*, 127 S. Ct. at 1740. Here, Philips, itself, teaches away from the addition that the rejection is seeking to make with Winston.

Following the above arguments regarding obviousness, Appellants respectfully believe that there is no "clear and particular" teaching or suggestion in Winston to incorporate the features of

Philips, and there is no "clear and particular" teaching or suggestion in Philips to incorporate the features of Winston.

For all of these reasons, the combination of Winston and Philips do not suggest the vascular repair device as recited in claim 20 of the present application.

Insofar as claims 21, 24, 44, 55, and 85 to 87 are ultimately dependent upon claim 20, it is respectfully believed that this claim is allowable based upon this dependency.

CONCLUSION

The remaining cited references have been reviewed and are not believed to affect the patentability of the claims as amended.

In this Response, Applicants have amended certain claims. In light of the Office Action, Applicants believe these amendments serve a useful clarification purpose, and are desirable for clarification purposes, independent of patentability. Accordingly, Applicants respectfully submit that the claim amendments do not limit the range of any permissible equivalents.

Applicants acknowledge the continuing duty of candor and good faith to disclosure of information known to be material to the examination of this application. In accordance with 37 CFR §1.56, all such information is dutifully made of record. The foreseeable equivalents of any territory surrendered by amendment are limited to the territory taught by the information of record. No other territory afforded by the doctrine of equivalents is knowingly surrendered and everything else is unforeseeable at the time of this amendment by the Applicants and their attorneys.

Applicants respectfully submit that all of the grounds for rejection stated in the Examiner's Office Action have been overcome, and that all claims in the application are allowable. No new matter has been added. It is believed that the application is now in condition for allowance, which allowance is respectfully requested.

If an extension of time for this paper is required, petition for extension is herewith made.

The extension fee for response within a period of two (2) months pursuant to Section 1.136(a) in the amount of $460.00 in accordance with Section 1.17 is enclosed herewith.

Please charge any other fees that might be due with respect to Sections 1.16 and 1.17 to the Deposit Account of Mayback & Hoffman, P.A., No. 503,836.

PLEASE CALL the undersigned if discussion would expedite the prosecution of this application or in the event the Examiner should still find any of the claims to be unpatentable, in which case, if possible, patentable language can be worked out.

Respectfully submitted,

For Applicants
August 13, 2008

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